

LABEL IN PART: (Vial) "30 cc Sterile Solution Each cc contains Anterior Pituitary. . . . 25 gr. Whole Ovarian. . . . 55 gr. Chlorobutanol 0.5% Note: There is no scientific evidence available that this product has therapeutic or physiologic activity. For Intramuscular Use Only Caution: Federal law prohibits dispensing without prescription."

LIBELED: 8-6-54, S. Dist. Ohio.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 9-15-54. Default—destruction.

4645. Aqueous extract of anterior pituitary. (F. D. C. No. 37297. S. No. 83-980 L.)

QUANTITY: 26 vials at Kansas City, Mo.

SHIPPED: Between 6-1-52 and 8-13-53, from Kansas City, Mo., by Ashe Lockhart, Inc., to Minneapolis, Minn., and from there reshipped to the consignee's Kansas City office.

LABEL IN PART: (Vial) "10 c. c. Aqueous Extract of Anterior Pituitary Each c. c. contains water soluble extractives from 18½ grains fresh tissue. Contains .5% Chlorobutanol (Chloroform Derivative)."

LIBELED: On or about 10-14-54, W. Dist. Mo.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 12-31-54. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4646. Phenobarbital tablets. (F. D. C. No. 37344. S. No. 77-275 L.)

QUANTITY: 1,100 100-tablet btls. and 1 10,000-tablet tin at Skillman, N. J.

SHIPPED: 10-19-53, from Brooklyn, N. Y., by Robin Pharmacal Corp.

RESULTS OF INVESTIGATION: The tablets had been shipped in bulk; and, upon receipt by the consignee, a number of the tablets were repackaged into bottles.

LIBELED: 11-10-54, Dist. N. J.

CHARGE: 501 (b)—the strength and quality of the article when shipped differed from the standard for phenobarbital tablets set forth in the United States Pharmacopeia since the article failed to meet the test for permissible variations in the weight of individual tablets and some tablets contained more and some tablets contained less than the declared amount of phenobarbital.

DISPOSITION: 12-10-54. Default—destruction.

4647. Triple hormone suspension. (F. D. C. No. 37464. S. No. 63-593 L.)

QUANTITY: 80 vials at Memphis, Tenn.

SHIPPED: 7-19-54, from Chicago, Ill., by Maizel Laboratories.

LABEL IN PART: "10 cc. Vial Intramuscular * * * Triple Hormone Suspension Each cc. Contains: Estradiol 1.2 Mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 77 percent of the labeled amount of estradiol.